

IN THE SPECIFICATION

At page 1, please amend the title as follows:

--~~Bubble Detector System and Method of Evaluation or Calibration Thereof Evaluating or Calibrating a Bubble Detector.~~--

At page 1, before the "Field of the Invention", please insert the following:

--Cross Reference To Related Applications

This patent application is a divisional of U.S. Patent Application Serial No. 10/610,084, filed on June 30, 2003, which is a divisional of U.S. Patent Application Serial No. 09/813,072, filed on March 20, 2001, now U.S. Patent Serial No. 6,622,542, issued September 23, 2003.--

On page 19, please amend the first paragraph, lines 1 through 12, as follows:

-- Referring now to Fig. 2, a block diagram representing various components of the system 10 is illustrated. An appropriate draw tube 34, such as ~~a cannula or catheter~~ an introducer sheath, is inserted into an appropriate blood vessel 36 of a patient 38. Blood is drawn from the patient 38 through the draw tube 34 using the blood pump system 24. Specifically, the blood pump system 24 includes a pump 40, such as a peristaltic pump. As the peristaltic pump 40 mechanically produces waves of contraction along the flexible tube 34, fluid within the tube 34 is pumped in the direction of the arrow 42. As will be discussed in detail below, the blood pump system 24 includes a flow meter 46 that receives feedback from a flow probe 48. The flow probe 48 is coupled to the patient's return tube 50, ~~such as a cannula or catheter~~. With this feedback, the blood pump system 24 can operate as an automatic extracorporeal circuit that can adjust the r.p.m. of the peristaltic pump 40 to maintain the desired blood flow. --

On page 19, please amend the second paragraph, starting on line 14 and ending on page 20, line 3, as follows:

-- The draw tube 34 and/or the return tube 50 may be sub-selective catheters. The construction of the return tube 50 may be of particular importance in light of the fact that the gas-enriched bodily fluid may be gas-saturated or gas-supersaturated over at least a portion of the length of the return tube 50. Therefore, the return tube 50, in particular, is typically designed to reduce or eliminate the creation of cavitation nuclei which may cause a portion of the gas to come out of solution. For example, the length-to-internal diameter ratio of the catheter may be selected to create

a relatively low pressure drop from the oxygenation device 54 to the patient 38. Typically, the catheter is sized to fit within a 6 french guide catheter. Materials such as polyethylene, or PEBA~~X~~ (polyetheramide), or silic~~e~~one, for example, may be used in the construction of the catheter. Also, the lumen of the catheter should be relatively free of transitions that may cause the creation of cavitation nuclei. For example, a smooth lumen having no fused polymer transitions typically works well. --

On page 63, please amend the second paragraph, starting on line 12 and ending on page 64, line 3, with the following paragraph:

-- The strength of the received signal on the line 1022 relative to the transmitted signal on the line 1020 provides information regarding the presence of bubbles within the return tube 50. As illustrated in Fig. 54, the bubble sensor 76 includes an ultrasonic transmitter 1040 and an ultrasonic receiver 1042. The bubble sensor 76 is advantageously disposed on the outside of the return tube 50. Thus, the ultrasonic signal from the transmitter 1040 is transmitted through the return tube 50, as well as any fluid within the return tube 50, to the receiver 1042. If the fluid in the return tube 50 contains no bubbles, the ultrasonic signal propagates from the transmitter 1040 to the receiver 1042 in a relatively efficient manner. Thus, the signal strength of the return signal delivered by the receiver 1042 on the line 1022 is relatively strong. However, if the fluid within the return tube 50 contains bubbles 1044, as illustrated in Fig. 55, the ultrasonic signal received by the receiver 1042 will be ~~weaker~~attenuated. The ~~poorer~~attenuated transmission of the ultrasonic signal across fluid containing bubbles results from the fact that the bubbles 1044 tend to scatter the ultrasonic signal so that less of the transmitted signal is ultimately received by the receiver 1042. --

On page 64, please amend the second paragraph, lines 5 through 13, as follows:

-- As illustrated by way of example in Fig. 53, the first peak 1027A depicts a signal that was transmitted through fluid containing no bubbles, and the second peak 1027B depicts a signal that was transmitted through fluid containing bubbles. The relative weakness of the peak 1027B is demonstrated by a reduction in the peak 1027B. The ~~extent of the reduction in the~~attenuation of peak 1027B is related to the diameter of the bubble passing through the bubble sensor 76 at the time the signal was transmitted. Specifically, the ~~amount of the reduction~~1046~~attenuation~~ in the signal is related to the the bubble's cross-sectional area and thus square of the diameter of the bubble, so that the square root of the signal is directly proportional to the ~~size of the bubble~~diameter. --

On page 65, please replace the fourth paragraph, starting on line 19 and ending on page 66, line 7, with the following paragraph:

-- Once the DSP 1000 determines the diameter of each bubble detected, it calculates the volume of the bubble. However, it should be understood that the volume of the bubble delivered to the patient 38 is affected by the pressure of the fluid within the return tube 50. Because the pressure of the fluid within the return tube 50 is typically higher, e.g., approximately two to three atmospheres, as compared to the blood within the patient's vessels, e.g., approximately one atmosphere, a conversion is advantageously performed to determine the volume of the bubble once it reaches the patient 38. Since the pressure in the return tube 50 is delivered to the bubble detector 74 on the line 1002, and since the pressure of the patient's blood can be assumed to be one atmosphere using the ideal gas law, the volume of the bubble at the patient equals  $V_p = (P_s \cdot V_s)/P_a$ , where  $V_p$  is the volume of the bubble at the patient 38,  $P_s$  is the pressure at the bubble sensor 76,  $V_s$  is the volume of the bubble at the bubble sensor 76, and  $P_a$  is atmospheric pressure. --

On page 66, please replace the third paragraph, starting on line 18 and ending on page 67, line 7, with the following paragraph:

-- The bubble detector 74 also may ~~add the volume of each bubble to a running total~~ accumulate total volume of all bubbles detected over time. If the ~~running total~~ accumulated volume exceeds a prescribed volumelimit within a prescribed time, then operation of the system 10 may be altered. For example, if the total volume of bubbles exceeds 10 microliters in a 90 minute period, the bubble detector 74 may deliver a "request to stop" signal on a line 1050. In this embodiment, the request to stop signal is received by the interlock system 44, so that the interlock system 44 can shut down the system 10 as previously described. Since most patients typically resolve small volumes of gas over time, the running total may be decremented as the procedure progresses so that the predetermined limit which triggers shut down of the system 10 will not be reached as rapidly. In addition, prior to reaching the predetermined limit, the bubble detector 74 may provide an early warning of an impending shut down so that the system controller 55 can lower the  $pO_2$  level of the blood in the return tube 50 to curtail bubble production and, thus, avoid shutdown. --

On page 72, please replace the third paragraph, lines 16 through 22, with the following paragraph:

-- An alternative embodiment of the calibration and evaluation system 1105 is identical to the previously described system except for the incorporation of a pulse dampener 1180, as illustrated in Fig. 59. The pulse dampener 1180 reduces or eliminates pressure oscillations produced by the pump

1120. In addition, Relatively large bubbles that may be produced by such pressure oscillations recirculated within the flow circuit become trapped within the pulse dampener 1180 so that they do not disturb the controlled formation of bubbles by the bubble-forming device 1143. --